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Report Highlights:

The Government of Argentina (GOA) approved three new Genetically Engineered (GE) events in 2021 (two corn events and one alfalfa). In November 2021 GE wheat flour containing the HB4 event from the company Bioceres, received approval by the Brazilian regulatory agency CTNBio. The approval raised concerns among several Argentine farmer organizations and exporters; therefore in order to strengthen controls of this wheat variety, the GOA has created an audit commission, which will operate within the National Seed Institute (INASE).

EXECUTIVE SUMMARY

2021 marks 25 years since the first Genetically Engineered (GE) crop was approved in Argentina in 1996. With more than 26 million hectares planted with GE soybean, corn, and cotton crops, Argentina is one of the three leading countries in the use of GE crops. The GE adoption process began in 1996 with the introduction of herbicide tolerant soybeans, and since then it has shown an unprecedented growth in area planted: 100 percent of soybeans, 99 percent of corn and 100 percent of cotton planted in Argentina are GE.

A report published in May 2021 by experts from the Bolsa de Cereales de Buenos Aires (*Buenos Aires Grain Exchange*) shows that GE crops bring economic benefits, simplify processes, and reduce the use of agrochemicals.

On October 7, 2020, Argentina became the first country in the world to approve GE wheat when the GOA approved HB4 Eco Wheat from the Argentine company *Bioceres Crop Solutions*. This full approval (for cultivation, food safety, processing, commercial sale, etc) was contingent upon approval in Brazil (Argentina's main market for wheat). Brazil granted partial approval (flour derived from the wheat) to this event in November 2021, among concerns from Brazilian millers' associations. In Argentina as well, the approval raised concerns among several farmer organizations and exporters, as they understand this approval might put Argentine wheat exports at risk in other markets. The exact status the HB4 wheat in Argentina is uncertain since Brazil has not yet approved the importation and sale of the wheat in form of grain. Over the last five years Brazil imported approximately 305,000 metric tons of flour per year compared to 5 million tons of wheat as grain. In November 2021, Argentina announced new rules for the control of HB4 wheat currently being cultivated in the country.

During 2020 and 2021, the Government of Argentina (GOA) continued to update the biotechnology regulatory framework to improve harmonization with international instruments, in particular, the Cartagena Protocol on Biosafety. In general terms, the update applies to products of genome editing technologies and eliminates the requirement for separate approvals of stacked biotech events. This update provides the country with a significant comparative advantage for the development and establishment of biotechnological ventures.

The seed royalty system continues to be an unresolved issue in the country. Argentine law allows farmers to save and replant seed and does not offer intellectual property protections for GE seed. Despite intense debate, Congress did not pass a new seed law before elections in October 2019, and has not discussed the proposal since the beginning of the COVID-19 pandemic.

China's approval of GE events continues to be a top trade priority for Argentina due to its importance as an export market for Argentine biotech-derived agricultural products. Since 2015, the Government of Argentina (GOA) has included a conditional statement in every approval of a soybean GE event that the event must be approved in China before domestic commercialization.

TABLE OF CONTENTS

CHAPTER1: PLANT BIOTECHNOLOGY PART A: PRODUCTION AND TRADE

- a) PRODUCT DEVELOPMENT
- b) COMMERCIAL PRODUCTION
- c) EXPORTS
- d) IMPORTS
- e) FOOD AID
- f) TRADE BARRIERS

PART B: POLICY

- a) REGULATORY FRAMEWORK
- b) APPROVALS
- c) STACKED or PYRAMIDED EVENT APPROVALS
- d) FIELD TESTING
- e) INNOVATIVE BIOTECHNOLOGIES
- f) COEXISTENCE
- g) LABELING and TRACEABILITY
- h) MONITORING AND TESTING
- i) LOW LEVEL PRESENCE (LLP) POLICY
- j) ADDITIONAL REGULATORY REQUIREMENTS
- k) INTELLECTUAL PROPERTY RIGHTS (IPR)
- 1) CARTAGENA PROTOCOL RATIFICATION
- m) INTERNATIONAL TREATIES and FORUMS
- n) RELATED ISSUES

PART C: MARKETING

- a) PUBLIC/PRIVATE OPINIONS
- b) MARKET ACCEPTANCE/STUDIES

CHAPTER 2: ANIMAL BIOTECHNOLOGY

- a) PRODUCT DEVELOPMENT
 - b) COMMERCIAL PRODUCTION
 - c) EXPORTS
 - d) IMPORTS
 - e) TRADE BARRIERS

PART E: POLICY

- a) REGULATORY FRAMEWORK
- b) APPROVALS
- c) INNOVATIVE BIOTECHNOLOGIES
- d) LABELING and TRACEABILITY
- e) ADDITIONAL REGULATORY REQUIREMENTS
- f) INTELLECTUAL PROPERTY RIGHTS (IPR)
- g) INTERNATIONAL TREATIES and FORUMS
- *h*) RELATED ISSUES

PART F: MARKETING

- a) PUBLIC/PRIVATE OPINIONS
- b) MARKET ACCEPTANCE/STUDIES

CHAPTER 3: MICROBIAL BIOTECHNOLOGY PART G: PRODUCTION AND TRADE

- a) COMMERCIAL PRODUCTION
- b) EXPORTS
- c) IMPORTS
- d) TRADE BARRIERS

PART H: POLICY

- a) REGULATORY FRAMEWORK
- b) APPROVALS
- c) LABELING and TRACEABILITY
- d) MONITORING AND TESTING
- e) ADDITIONAL REGULATORY REQUIREMENTS
- f) INTELLECTUAL PROPERTY RIGHTS (IPR)
- g) RELATED ISSUES

PART I: MARKETING

- a) PUBLIC/PRIVATE OPINIONS
- b) MARKET ACCEPTANCE/STUDIES

CHAPTER 1. PLANT BIOTECHNOLOGY

PART A: TRADE AND PRODUCTION

A) PRODUCT DEVELOPMENT

Argentina has several biotechnology companies that are researching new potential plant products, but due to the early-stage of their development little specific information is publicly available at this time.

B) COMMERCIAL PRODUCTION

Argentina is the world's third largest producer of biotech crops, after the United States and Brazil, with sixty-four biotech crop events approved for production and commercialization: sixteen soybean events, two alfalfa events, one safflower event, and one wheat event.

Introduction of biotech soybeans in the late 1990s sparked a rapid expansion of soybean production, which now surpasses 17 million hectares.

China's approval of GE events

China's approval of GE events continues to be a top trade priority for Argentina due to its importance as an export market. Argentina requires that biotech events be approved in China prior to any domestic commercialization. The industry and government consistently stress to Chinese authorities the importance of timely, science-based safety reviews for new events to avoid asynchronous approvals that lead to trade disruptions.

In recent years, the rate of Chinese approvals has lagged behind other importing countries, such as Mexico, Japan, and South Korea, hampering producers' access to new seed technologies. A 2018 analysis of the agricultural and broader economic impacts of the delays in Chinese biotech approvals can be found at:

https://croplife.org/?s=The+Impact+of+Delays+in+Chinese+Approvals+of+Biotech+Crops

Soybeans

Released in 1996, glyphosate tolerant soybeans have been adopted at a very high rate in Argentina and encompass all of the estimated 17.1 million hectares of soybeans planted for the 2019/2020 season. Furthermore, the new technology facilitated double crop soybeans (allowing soybeans to be planted following wheat harvest) in many areas where only one crop was planted before the availability of GE varieties.

After the introduction of glyphosate-tolerant soybeans, one of the most important technological leaps in soybean production occurred in 2012 with the authorization to commercialize soybean seeds, products and by-products with stacked insect resistance (IR) and herbicide tolerance (HT) events. In the last four seasons, the use of varieties using stacked IR and HT soybean events has reported significant growth: from 7 percent in the 2014/15 season, to 20 percent in the 2019/20 season. Farmers in the northeastern region of Argentina where there is high incidence of

lepidoptera have the highest adoption levels of stacked soybean varieties. Adoption rates decrease incrementally going from northern to southern Argentina.

The Argentine soybean industry is oriented almost entirely towards exports. Twenty percent of soybeans are exported as whole beans while eighty percent is crushed and exported as meal or oil. The great majority of soybean oil and meal is exported, with a small remainder (7 percent of total meal and oil supplies) directed to local feed operations. For more detailed information on soybean production, please see the Argentina Oilseeds and Products Annual Report:

https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Oilseed s%20and%20Products%20Annual Buenos%20Aires Argentina 04-15-2021

Corn

Argentine farmers have been using stacked corn events for over ten years. Two new events were approved in November 2021, both from Monsanto/Bayer Argentina:

MON-87427-7 xMON-89Ø34-3 xSYN-IR162-4 xMON-87411-9 xMON-87419-8 xMON-ØØ81Ø-6, and MON-87427-7 x MON-87419-8 x MON ØØ6Ø3-6.

Over the last decade, there has been a dramatic change in the adoption of maize stacked events. The development of new stacked events contributed to a decrease in the use of single events at the expense of stacked events. In the 2019/20 season, stacked HT and IR events accounted for 92 percent of total corn planted, while single events accounted for 7 percent and conventional seed accounted for 1 percent.

Stacked events have been adopted across all regions of Argentina. These stacked events reduce the number of treatments and amount of crop protection products applied and consequently their associated costs. Use of stacked events also allows for better crop health, higher yield potential and an easier drying process. Likewise, the use of stacked events for insect and weed control becomes important in late-planted corn crop production systems. While a later planting date can permit more flexibility in choosing the date of sowing and harvesting, and in selecting the best conditions of temperature, soil moisture, etc. it exposes crops to higher pressure from insect pests, such as stem borer, armyworm, and bollworm.

Cotton

In the 2019/20 crop season, the total cotton area was planted with the stacked HT and IR events. No new events were approved in 2021.

C) EXPORTS

Argentina is a net exporter of GE commodities to numerous markets in the world, including the United States. Export documentation for grains declares the GE content.

D) IMPORTS

With the exception of GE soybeans imported from Paraguay for use in the Argentine soy crushing industry, Argentina is not a major importer of GE crops. However, a severe drought during the peak summer months in 2018 reduced Argentine soybean production to 36 million tons, down 54 million tons from projected estimates. The Argentine soybean crushing industry needed to source beans to maintain its processing levels and imported soybeans in large quantities from the United States for the first time since 1997. To facilitate these imports, Argentine regulatory agencies enabled the possibility of granting approvals for food, feed and processing (FFP) without approval for cultivation. As a result, Argentina imported soybean varieties from the United States and Brazil containing events approved for FFP but not for cultivation. Developers of these soybeans did not seek their approval for cultivation due to Argentina's lack of Intellectual Property Rights (IPR) for plant varieties.

Import Policy

With the arrival of U.S. soybeans in 2018, entry protocols for GE events became a point of discussion. On May 18, 2018, the Ministry of Agro-Industry released Resolution 26/2018 <u>https://www.boletinoficial.gob.ar/detalleAviso/primera/183969/20180518%29</u>. This resolution permits the import of GE soybeans with events that have not been approved in Argentina, but that have been approved in other countries. These events may be used for FFP, but not cultivation. The resolution was authorized to be in effect for four years following its publication.

E) FOOD AID

Argentina is not a food aid recipient or donor and is not likely to be one in the near future.

F) TRADE BARRIERS

Post is unaware of any current trade barriers.

PART B. POLICY

A) REGULATORY FRAMEWORK

In 2020 and 2021 the GOA updated its regulatory framework for agricultural biotechnology through the following resolutions (links all in Spanish):

Resolution 44/19_(field trials of GE Plants) http://servicios.infoleg.gob.ar/infolegInternet/anexos/320000-324999/324699/norma.htm

Resolution 19/2021(Isolation Conditions for confined activities) https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-19-2021-346692

Resolution 32/2021 (Environmental risk assessment, including regulation for stacks)

https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-32-2021-347662

Resolution 49/2021 (Management of insect resistance) https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-49-2021-349663

Since 2012, the evaluation of new GE events has taken place on a case-by-case basis. Argentine biotechnology regulations are based upon the characteristics and of GE products and their potential risks to human health, animals, and the environment, as compared to risks presented by their conventional counterparts.

The Coordination of Biotechnology and Innovation is the focal point for all Argentine biotechnology regulations and information. It is housed within the National Directorate of Bioeconomy, which in turn is housed within the Ministry of Agriculture This office coordinates three technical areas: biosafety (the head is a member of the *National Advisory Committee on Agricultural Biotechnology, (CONABIA),* policy analysis and formulation, and regulatory design.

The approval process for commercialization of biotech seeds involves the following agencies within the Ministry of Agriculture:

-National Advisory Committee on Agricultural Biotechnology (CONABIA)

CONABIA's main responsibility is to assess the potential environmental impact of the introduction of biotech crops in Argentine agriculture. CONABIA advises the Secretary of Food and Bioeconomy on issues related the release of GE crops and biotechnology-derived products into the environment. CONABIA has been recognized by the Food and Agriculture Organization of the United Nations (FAO) as a Center of Reference for the biosafety of GE events.

CONABIA is a multi-sectorial organization made up of representatives from the public sector, academia, and private sector organizations. Its members perform their duties as individuals and not as representatives of any organization. They are active participants in international discussions on biosafety and related regulatory processes.

Under Argentina's regulatory framework, CONABIA must complete its evaluations of GE products in 180 days. CONABA has adopted an electronic form system that allows all agencies to access documents at the same time, further accelerating the approval process. CONABIA has reviewed over 2,100 permit applications since its creation. CONABIA is an advisory agency that operates pursuant to a resolution issued by the Argentine Ministry of Agriculture.

-National Service of Agricultural and Food Health and Quality (SENASA) SENASA evaluates the safety of products derived from GE crops for human and animal consumption.

-National Directorate of Agricultural Food Markets (DNMA) (Dirección Nacional de Mercados Agroalimentarios in Spanish)

DNMA evaluates commercial impacts of GE product approvals on Argentine export markets. DNMA mainly analyzes the approval status of new events in key destination markets, such as China and Brazil, in order to determine if Argentine production of the events in question would restrict Argentina's market access. Under Argentina's regulatory framework, DNMA provides an evaluation within 45 days.

-National Seed Institute (INASE)

INASE establishes requirements for seed registration in the National Registry of Cultivars.

Once GE products have been evaluated by all of the entities listed above, the Coordination of Biotechnology and Innovation compiles all pertinent information. The Coordination then prepares a final report to the Secretary of Bioeconomy, Food and Regional Development, who makes a final decision for GE product approvals.

B. APPROVALS

All biotech events in Argentina must receive technical approval for safe use in the environment, for human, animal, and crop health, and then receive commercial approval that their use will not disrupt Argentina's major export markets. The Ministry of Agriculture publishes a list of events that are approved, both technically and commercially. Since 2015 all soybean approvals have been additionally conditioned on Chinese approval prior to these events being planted commercially in Argentina. Thus, even fully approved soybean events cannot be planted until Chinese approval is granted. Similarly, the GOA approved on Oct 2020 the new HB4 Eco Wheat drought contingent upon approval in Brazil (Argentina's main market for wheat). Despite Brazil granting approval to wheat flour containing the HB4 event in November 2021, the event has not been fully deregulated in Argentina as discussed below.

For a full list of approved GE crops in Argentina, see the annex at the end of this report.

First approval of a wheat event in the world

The Argentine company *Bioceres Crop Solutions* developed the HB4 wheat under a joint venture with the French company *Florimond Deprez*. The wheat is drought tolerant and is tolerant to ammonium glufosinate. The company reports that the crop can sustain good yields even in case of severe drought, displaying up to a 40% greater yield as compared to non-GE wheat in similar conditions.

The HB4 gene was originally isolated from sunflower and has been introduced to wheat, soybeans, and corn. Soybeans with the HB4 gene are currently being multiplied in both Argentina and the United States, with the expectation of a commercial release in the near future. In the United States, this business is being conducted as part of a joint venture between the *Instituto Agrobiotecnológico Rosario (INDEAR)*, which is the research and development branch of *Bioceres*, and *Arcadia AgroSciences*.

The HB4 wheat approval was surrounded by controversy, since Argentina's wheat producers and millers are concerned that being the first country to commercialize GE wheat will affect its export markets. Argentina is in a unique position to commercialize GE wheat because Brazil, a country generally supportive of biotechnology, accounts for around 43 percent of Argentina's

wheat exports. For that reason, the effective entry into force of the commercial approval was conditioned to the Brazilian approval of the crop; this strategy that has been used previously by the country on its approvals of GE soy, which are conditioned to the Chinese approval.

On November 11, 2021 the Brazilian National Biosafety Commission (CTNBio) unanimously endorsed biosafety conditions for flour obtained from HB4 Wheat. The comprehensive regulatory process addressed allergenic risk concerns and demonstrated the safety equivalence of HB4 wheat to its conventional counterpart. In Argentina, the approval raised concerns among several farmer organizations and exporters, as they understand this approval might risk Argentine wheat exports. The grain export chamber asked that Bioceres be required to disclose the locations of all HB4 wheat plots. In an investor document published in November 2021, Bioceres said ~55,000 hectares were planted with HB4 wheat in Argentina by 225 farmers in the 2021/22 crop year. https://investors.biocerescrops.com/events-and-presentations/default.aspx

In order to address these concerns, the GOA created an audit commission, which will operate within the National Seed Institute (INASE). INASE issued Resolution 535/2021, to set tight controls of the activities with the HB4 wheat. In general terms this resolution sets the following parameters of control:

The developer of the product must report the current inventory of stocks in each of the processing plants and/or storage places with geo -reference of their location, reporting of any classified material, unclassified material, discards and purge materials.

The developer may keep up to twenty percent as seed, identifying, in that case, the place of storage and its conditions, in order to allow control and verification. For the 2021/2022 crop season, the conservation of up to half of the harvested volume is authorized as "propagation material", and the company is in charge of the processing (with loss of germination power), and final destination of the remainder subsequently informing the Commission.

The owner of the harvested material shall report the results of the purges carried out to the harvesting equipment and processing plants, as well as the cleaning of the storage places of the material. The company also shall report, at the request of the Commission, the results of the analyses carried out on the purge material in order to verify compliance with the established confinement.

Complete text of Resolution 535/21 can be found at: https://www.boletinoficial.gob.ar/detalleAviso/primera/253893/20211203

First Chinese soybean event approved in Argentina

Since 2013, *Bioceres Crop Solutions*, the flagship of the local biotech industry and *Beijing Da-Bei-Nong Technology Group (DBN)* have partnered to facilitate regulatory approval of DBN's biotech events in Argentina and *Bioceres*' biotech events in China.

In February 2019, DBN's soybean event DBN 09004-6, a trait to confer tolerance to glyphosate and glufosinate-ammonium herbicides in soybeans, received technical and commercial approval

in Argentina. It is the first Chinese-developed soybean event approved in Argentina. Later in 2021, China grated approval to this event, which is the first event that received approval for planting in China.

In 2015 the Ministry of Agriculture announced a regulatory approach to products of genome editing. Since then, <u>Argentina has designated many products developed with this technology as being "non-genetically modified," as is shown by</u> Whelan, A. I., Gutti, P., & Lema, M. A. in their 2020 paper, *Gene editing regulation and innovation economics*. For more information on Argentina's regulatory approach to products of genome editing, see Chapter I, Part B, section e.

C) STACKED OR PYRAMIDED EVENT APPROVALS

Historically, approvals of stacked events were decided on a case by case evaluation under which the applicant would submit a letter simultaneously to the Ministry of Agriculture (Coordination of Biotechnology and Innovation, and SENASA requesting technical and commercial approval of the specific stacked event. The evaluation was based on possible metabolic interactions between the individual events contained in the stacked event. Also, to evaluate the possible effects of the stacked event in the ecosystem, as well as the food biosafety evaluation, CONABIA and/or SENASA would determine whether additional information from the applicants is required. A new regulation approved in late 2019 changed the way that stacks are assessed and approved, and eliminated the need to assess or approve stacked of events that have been approved previously as individual events, and that are considered to have a low risk of interacting negatively with other events. With this approach Argentina aligned itself with the United States, where most stacked events do not require an additional approval (unless they combine insecticidal proteins). This update provides the country with significant comparative advantage for the development and establishment of biotechnological ventures.

Resolution 32/2021 (Environmental risk assessment, including regulation for stacks) https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-32-2021-347662

D) FIELD TESTING

In Argentina field testing of GE crops is performed by many local and international developers, with an average of 60 applications per year, each including dozens of release sites hundreds of different events. It is a permit-based system, where developers must present an application that has to be evaluated and approved case by case. The list of field trial applications currently being assessed is not public information. Local field trials are necessary for the approval of new transformation events, but not for new stacks of previously approved events. The number of local field trials can be reduced by combining information from field trials performed in other countries.

E) INNOVATIVE BIOTECHNOLOGIES

In 2019, Argentina presented a declaration in the plenary of the WTO SPS committee (WTO document code G/SPS/GEN/1699). It was issued by the Ministers of Agriculture of Argentina,

Brazil, Chile, Paraguay and Uruguay, all of which are members of the Agricultural Council of the South (CAS). The declaration notes the signatory countries' strong support of genome editing and other innovative breeding techniques and is in line with the 2018 International Statement on Agricultural Applications of Precision Biotechnology, which Argentina presented to the WTO on behalf of a group of 10 countries, including the United States.

Argentina's Regulatory System for Products Derived from Innovative Biotechnologies

In 2015, Argentina became the first country in the world with a "GE-trigger" (Cartagena Protocol compliant) regulatory system to adopt explicit criteria establishing that certain products obtained with genome editing techniques are not GE. To date, six other Latin-American countries (Chile, Brazil, Colombia, Paraguay, Honduras, and Guatemala) have followed this lead and enacted similar regulations.

In accordance with Argentina's status as one of the most sophisticated regulatory systems in the world, Argentine policymakers and regulators debated for over three years to clarify the status of products derived from "new breeding techniques (NBTs)", such as genome editing, under the existing biotechnology regulation. During the debate, policymakers and regulators noted that no disagreements emerged in interpreting the terms "living modified organism" or "modern biotechnology" (which in practice means the use of recombinant DNA at some step of the breeding process). However, the interpretation of the phrase "novel combination of genetic material," was a matter of debate.

As a result, "novel combination of genetic material" is the critical factor for Argentina in deciding whether a product derived from "NBTs" (where "NBTs" are new techniques that use DNA manipulation as an aid during the breeding process) is a should be regulated as a "living modified organism". The following are the main foundational criteria under the new Argentine regulation:

- Cartagena Protocol Definition

For transboundary movements of GE and genome edited crops, Argentina currently bases its regulation on language similar to that in the Cartagena Protocol on Biosafety.

- Flexibility for Future Technologies

Argentina does not maintain a reference list of techniques considered to be "NBTs", as new technologies have emerged rapidly. For instance, in many of the initial lists of "NBTs" created in the mid-2000s, the CRISPR-Cas9 system was not included, since that technology was not available. However, the CRISPR-Cas9 system is currently one of the most promising "NBTs". In addition, although in scientific papers a technology's name may be perceived as a clear denomination, discussion with policymakers in Argentina revealed that it was not easy to produce "satisfactory" (technically clear, fit for purpose) legal definitions of the various technologies. Therefore, Argentina decided that a new regulation on "NBTs" should not be based on a closed list or description of particular technologies, but instead should be framed to be flexible and applicable to existing or forthcoming technologies as much as possible.

- Case by Case Analysis

Although certain technological terms such as "Cisgenesis," "Reverse Breeding," "Site Directed Nucleases" may be satisfactory for a scientific discussion, when comparing different uses of an "NBT" by different research groups, differences from one case to another made it difficult for Argentina to adopt legal definitions for these technologies for regulatory purposes. For similar reasons, Argentina found it difficult to arrive at a "technology-broad" criterion regarding the regulatory status of end products since these can differ significantly.

Argentina determined that the analysis to establish whether a certain genome edited crop is subject to regulations for "Genetically Modified Organisms (GMO)" could only be made on a product by product basis. So far, Argentina has evaluated several plants produced by "NBTs", and all were excluded from the "GMO" regulation and deemed applicable for review under conventional processes.

Resolution 21/2021 of the Secretariat of Food, Bioeconomy and Regional Development established procedures to determine the criteria under which crops obtained by breeding techniques involving modern biotechnology do not fall under "GE" regulation.

https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839

This regulation was developed with the intention of improving the previous regulation. To this end, applicants submit each product ("NBT"-derived crop) to establish whether the result of the breeding process is a new combination of genetic material or not. Resolution 21/2021 highlights the following characteristics:

- The procedure determines if a product obtained by an "NBT" should be evaluated as a "GMO"
- The analysis is carried out on a case-by-case basis.
- It is not restricted to a specific list of techniques.
- Allows consultation during the design stage of products.
- The Commission must provide with a response within 80 working days.
- Uses the definitions of "LMOs/GMOs" from the Cartagena Biosafety Protocol.

A genetic change is regarded as a new combination of genetic material when a stable and joint insertion of one or more genes or DNA sequences that are a part of a genetic construct are introduced permanently into the plant genome. With this criteria, GMO products containing INDELS, nucleotide substitutions, and ALLELE replacements have been excluded from the

regulation. Also, if appropriate, the existence of sufficient scientific evidence must support the absence of transgenes that may have been used transiently during the crop breeding process.

The procedure includes an 80 day time limit, after which the applicant receives a reply from the authorities stating if the described product falls under the biotechnology regulation. If the product is not regulated as a "GMO", but its features and/or novelty lead to a significant risk hypothesis, this must be also reported by the regulatory commission. This report is channeled to the appropriate regulator of varieties obtained by "conventional" breeding for consideration.

For projects in the design stage, applicants may file inquiries aimed at a preliminary assessment of whether the expected product might be regulated as a "GMO". When the new crops are finally generated, the applicant must still submit factual determinations about its genetic makeup. In the event that the product possesses the features anticipated in the preliminary inquiry, the earlier assessment regarding its regulatory status would remain.





Source: Whelan, A. I., & Lema, M. A. (2019). Regulation of genome editing in plant biotechnology: Argentina. In *Regulation of Genome Editing in Plant Biotechnology* (pp. 19-62). Springer, Cham

Conclusions on the experience of dealing with "NBTs" in the last 6 years

• 32 cases have been presented and evaluated to date, including real and hypothetical cases.

- This regulation gives certainty to local developers because the prior consultation instance allows them to predict costs and development time even at the design stage. This has allowed companies to present cases in a wide variety of crops, with diverse phenotypes.
- Increased the number of animal and microorganism consultations, with a predominance of consultations for local developments.

F) COEXISTENCE

Argentina has no regulations governing coexistence.

G) LABELING AND TRACEABILITY

Argentina has no regulations regarding the labelling of GE products. The current regulatory system is based on the characteristics and identified risks of the product and not on the development process.

The Ministry of Agriculture's position on labelling is that it should be based on the type of food product derived from a specific GE event taking into account that:

- Any food product obtained through biotechnology and substantially equivalent to a conventional food product should not be subject to any specific mandatory label.
- Any food product obtained through biotechnology and substantially different from a conventional food product for any specific characteristic may be labelled according to its characteristics as a food product, not according to aspects concerning the environment or production process.
- Differential labelling is not justified as there is no evidence that demonstrates that food products produced through biotechnology may represent any risk for the consumers' health.
- In the case of agricultural products, of which the majority are commodities, the identification process would be complicated and expensive. The increased production costs due to labelling would be paid by consumers without necessarily providing better information or increased food security.

H) MONITORING AND TESTING

There is no official traceability system in place. Exporters provide an affidavit stating the GE content of the shipment. There are private companies (authorized labs) which have the capability to perform the required tests, and the National Institute of Agricultural Technology (INTA) does

analysis on a private basis. To date, there are no provisions for monitoring genome edited products.

Since 2016, biotech testing of some export shipments has been conducted under the *Bolsatech* program. This is not intended to identify unapproved events but is meant to help recuperate costs for technology providers since IPR rights for biotech seed in Argentina are difficult to enforce. *Bolsatech* is a voluntary system implemented by the Grain Board of Trade that assures that seed companies will be able to collect royalties and provides farmers different options to pay for the technology. Farmers can choose either advance payment or at the point of delivery. Payment for the technology at point of delivery is used by those farmers that did not purchase certified seed but have used it without permission. If detected, they have the option of paying at port and *Bolsatech* provides additional testing and arbitration. For those farmers who do not join the *Bolsatech* system and test positive at port, the payment is automatically deducted (or the shipment is rejected) under agreements between the seed companies and the exporters.

I) LOW LEVEL PRESENCE (LLP) POLICY

Intra Mercosur Regulation on setting a mechanism to decrease occurrence of presence in Low Level Presence of GE products between states parties

Based on a proposal from Argentina Mercosur members signed resolution MERCOSUR/GMC/RES. Nº 23/19 in order to set a mechanism to decrease occurrence of presence in Low Level Presence of GE organisms between states parties. This Resolution establishes an operating mechanism that member countries must implement to avoid LLP situations with GE products.

When there is commercial authorization that includes use in human and/or animal feed of GE products in any member country, the latter must inform the other member countries of said authorization, within the scope of the Committee on Agriculture Biotechnology (CBA) of the Working Subgroup N 8 "Agriculture (SGT N 8), within 30 calendar days from the date of authorization.

When communicating on the aforementioned authorization, the member country must send to the CBA, the appropriate risk assessment carried out by the national body responsible for biosafety, the information on the status of approval of the event in the main markets of export, and the information submitted by the applicant, excluding information classified as "confidential"

For the implementation of this mechanism, the developers of the authorized event must have previously submitted the request for commercial evaluation of the product in the other member countries.

Having all aforementioned information, the CBA in each case must:

-Analyze possible LLP situations of the GE event that may occur in the region.

-Recognize the risk assessment of the member country as input for a decision making.

-Prepare a report to recommend exclusive approval for GE LLP situations. In that report, each member country may define maximum tolerance limits according to its convenience, as well as other technical recommendation it deems relevant. That report must be recorded as an annex to the CBA minutes.

In summary, this process aims at speeding up the synchronized approval of an event in the four countries of the MERCOSUR, once one member first approves a new product. This process does not entail sharing information on LLP incidents with third parties or for other purposes.

J) ADDITIONAL REGULATORY REQUIREMENTS

None.

K) INTELLECTUAL PROPERTY RIGHTS

The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotech inventions, renders Argentina's intellectual property system inadequate from the perspective of the biotechnology industry. Argentine Intellectual Property (IP) laws are based on UPOV-78 which provides strong protection for the right to save and replant seeds. Seed companies can register new varieties, but penalties for unauthorized use of protected seed varieties are negligible. Seed companies have tried to use contracts to ensure that seeds containing biotech events are only used by authorized purchasers. However, judicial enforcement of such contracts has proved ineffective as a mechanism to prevent the unauthorized commercial use of GE varieties in Argentina.

Seed Law

The seed royalty system continues to be an unresolved issue in the country. Despite intensive debate, Congress did not pass a new seed law before elections in October 2019. The latest seed proposal, sponsored by seed manufactures (via the Argentine Seed Association) and some of the major farmer groups, appears to provide clearer rules in the marketing of seed technologies and IPR protections. The proposed law facilitates producer's own use of seed by mandating that the price paid by producer for seed will cover the intellectual property rights of that product for a minimum period of three years. That is to say, when the producer purchases a bag of seed, he/she will pay for the rights to utilize the biotechnology, germplasm and products obtained from the seed for the three-year period or longer. Although the law does not limit the final use or transfer of seed technologies, it grants the right to the owner of the protected seed technology to require payment for the own use of seed in each subsequent propagation and/or seed multiplication. Indigenous people and producers registered under the National Family Farming registry (lowincome producers) are not obligated to pay for the seed technology. Another exception is allocated for the use of seed for research and development purposes. The proposal strengthens the authority of the National Seed Institute, allowing it to have access to any crop or its product to implement this law, sanctioning anyone who limits this effort or provides false information. However, this was not the only proposal that was submitted to Congress. There have been other drafts submitted, which do not have the consensus of the seed industry nor the farmer organizations. After the

failure to pass a new seed law before elections in October, it is unclear when the new Congress will begin debating the seed law, or what legislative draft will serve as the basis for discussion in the future.

Biosafety Law

The abovementioned regulations constitute the specific regulations for biosafety, and they are based on general laws on food safety and animal/plant health; this scheme is similar to the US regulatory framework. For this reason, there is no biosafety law in Argentina.

L) CARTAGENA BIOSAFETY PROTOCOL RATIFICATION

GOA officials are very active in working with the other countries of the region towards harmonization. Argentina signed the Cartagena Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet ratified it. Argentina is still undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take in this respect. It has become public that Argentina has been firmly working toward ratification of the Protocol. However, Post's contacts within GOA have estimated that this is very unlikely to occur in the near future.

M) INTERNATIONAL TREATIES/FORA

Argentina has not joined any new international treaties related to agricultural biotechnology.

N) RELATED ISSUES

Like-Minded Group on Innovative Agricultural Technologies with a focus on GE crops

A group of representatives of exporting countries met in Argentina in 2010 with the intention of setting the scope, aim, and priority issues of a like-minded group on innovative agricultural technologies with a focus on cloning and GE crops. Recognizing that agricultural production will need to substantially increase to meet global food demand, understanding that innovative agricultural technologies need to continue to play a critical role in addressing these challenges, and emphasizing that regulatory approaches should be science based, the group was successful in setting the basis for collaborative work in the areas of research and education, promotion of utilization of Codex regulations, and support of science based assessments of food, feed and environmental safety. As of 2019, the Like-Minded Group continued to be very active. For instance, there are periodic exchanges between agricultural attaches of Like-Minded countries in Brussels and China.

Declaration of the Ministers of Agricultural Council of the South (CAS) on Gene Editing

The Ministers of Agriculture of Argentina, Brazil, Chile, Paraguay and Uruguay, members of the (CAS), met in Buenos Aires, Argentina in March 2019 and agreed that:

- 1. Crops improved by genome editing have the potential to play a fundamental role in addressing the challenges of the agricultural production, contributing to increase the food supply in a sustainable manner.
- 2. Gene editing can generate crops analogous to those obtained through other conventional breeding methods.
- 3. CAS countries present public and private investment in the development of improved crops by genome editing. This is because it can accelerate the access of the agricultural producer to new characteristics of agricultural interest, while representing an opportunity

MaizALL Alliance between Producers in Argentina, Brazil and the United States

As corn exporting countries whose producers cultivate biotech crops, Argentina, Brazil, and the United States face many of the same trade barriers when exporting corn and corn co-products. As a result, producer organizations from these countries formed an international corn alliance called MaizALL to work together on the following issues:

1. **Global asynchronous and asymmetric approvals:** The governments and industry of Argentina, Brazil, and the United States need to present a unified voice in advocating to foreign governments of major importing countries to synchronize global approvals of biotechnology products and foster the development of policies that manage instances of low-level presence (LLP) of not yet approved biotech events.

2. **Harmonization of regulatory policies in the Americas:** Recognizing the need for harmonization of global regulatory approval processes for new biotech events, the United States and South American corn sectors would like to see a harmonization of regulatory policies in the Americas with the end objective of mutual recognition of biotech approvals.

3. **Communication on modern agriculture:** There is consensus on the need to provide better consumer understanding of production agriculture, including the benefits of biotechnology and advancing the global acceptance on the capacity to produce grain for feed, food and fuel.

Note: These are the positions of MaizALL.

PART C. MARKETING

A) PUBLIC& PRIVATE OPINIONS

Most Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotechnology to improve the yield and nutritional value of crops while decreasing inputs. Argentine consumers accept the economic benefits of biotech products but remain cautious about supporting the technology for food production. As Argentina has been a leader in the adoption of biotechnology, there is a need for dialogue and communication among scientists, farmers, private companies, consumers, government, and regulatory organizations.

Although there are no rejections or controversies around the safety of GE crops, there is increasing activism against the use of glyphosate, which disseminates a growing concern in the population. However, so far this seems to be just a misinformation campaign.

B) MARKETING STUDIES

Post is unaware of any relevant country specific studies on the marketing of GE plants and plant products. A study has been made on the prospective impact on innovation economy of gene-edited organisms of agricultural use: Whelan, A. I., Gutti, P., & Lema, M. A. (2020). Gene editing regulation and innovation economics. *Frontiers in Bioengineering and Biotechnology*, *8*, 303.

A group of experts from Bolsa de Cereales de Buenos Aires (Buenos Aires Grain Exchange), A. Tejeda Rodriguez, Santiago Rossi, Nicolas Jorge & Eduardo Trigo, presented a report on May 2021 the paper 25 Years of Genetically Modified Crops in Argentine Agriculture, showing the economic and environmental impact of the adoption of GE seeds in the Argentine agriculture in soybean, corn and cotton crops. They analyzed the effects for the farmers, the country and the environment.

The results of the study showed that In the period 1996-2020, GE crop production schemes outperformed conventional crop schemes on average by USD 29.1/ha for soybeans, USD 35/ha for maize, and USD 217/ha for cotton. Depending on the crop, the margin increase was attributed to a combination of lower production costs and higher yields.

A second set of results shows that the adoption of GE crops has brought significant benefits to the country. Cumulative gross margins in the period under analysis are estimated at USD 158 billion. Out of the total benefits, 92% (USD 146 MM) correspond to soybean cultivation, 7% (USD 10.9 MM) to corn, and the rest (USD 2.1 MM) to cotton. Considering the increase in foreign exchange due to higher exports, the 25 years of GE crop production represented an additional USD 153 billion. In terms of the additional employment demanded by value chains as a result of GE crops, an average of 93 thousand jobs was created per season.

A third group of results shows that in environmental terms, GE crops have made it possible to significantly mitigate the impact of primary production on the environment. Environmental benefits were estimated on two fronts. First, benefits are due to the reduced use and toxicity of agrochemicals applied to the soil. In this regard, the case of GE soybeans stands out, with a 30% environmental impact reduction compared to conventional soybeans. On the other hand, environmental benefits were estimated due to the enhanced adoption of no-till farming as a result of the use of GE crops. In this regard, benefits were identified from both the reduced use of fossil fuels and the increased rate of carbon sequestered in the soil that arises from applying this practice of conservation agriculture.

CHAPTER 2. ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

A) PRODUCT DEVELOPMENT

CONABIA reviewed only housekeeping applications for earlier projects pertaining bovines that carry a gene that produces human growth hormone in milk and "humanized" milk. An application on sheep was rejected because it was based on research activities that disregarded the local regulation, and therefore the applicant was instructed to halt the project.

There are currently 3 regulated projects active in Argentina:

1) Cows expressing production of growth hormones, rotavirus antibodies, and proteins (caseins) in milk that is intended for pharmaceutical uses and human consumption.

2) Cows that produce hypoallergenic milk by stopping expression of an allergenic protein (betalactoglobulin). This milk is intended for human consumption.

3) Sheep that express green fluorescent proteins. The sheep are used for research.

Argentina has been proactive on the issue of somatic cell nuclear transfer (SCNT) cloning, including collaboration between scientists of different Argentine research centers (mainly University of Buenos Aires, the University of San Martin, and INTA) with counterparts in the United States, Canada, Australia, New Zealand and the European Union, among others.

B) COMMERCIAL PRODUCTION

As of yet, there is no commercial production of GE animals in Argentina. A small number of cloned cattle have been sold commercially. Although more than 400 cloned cattle animals were generated in Argentina in previous years, currently there is almost no activity with this species, mostly due to concerns regarding trade barriers in the European Union. On the other hand, cloning activity is very intense in regard to polo horses, where about 300 animals have been generated.

C) EXPORTS

None

D) IMPORTS

None

E) TRADE BARRIERS

Post is unaware of any country specific trade barriers.

PART E: POLICY

A) REGULATORY FRAMEWORK

Argentina now has procedures in place for requesting the commercial approval of GE animals, as well as for excluding gene-edited animals from the regulation. This was enabled by Resolution 63/19 and by Resolution 21/21. Resolution 21/21 complements Resolution 63/19 and covers animals, plants and microorganisms. It specifically covers the public consultation instance, and provides different forms to be used by the developers.

With this update, the regulation for GE animals in Argentina perfectly mirrors the regulation for GM crops, having the same provisions for different kind of applications (field trials, commercial release) and products (gene-edited, stacks).

http://servicios.infoleg.gob.ar/infolegInternet/verNorma.do?resaltar=true&id=327185 (In Spanish)

https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-21-2021-346839/texto (In Spanish)

The concrete and simple form is designed to simplify the process for these developers. It will provide guidance, among other questions, on which regulations must be taken into account when applying for a permit and on the state of progress of the permits in progress. In addition, individuals or entities that plan to develop a product using Modern Biotechnology tools can find out whether their product or activity should be regulated by CONABIA or not. After completing it, an e-mail will be sent to a specific mailbox of the Coordination of Innovation and Biotechnology and a response will be sent to guide the way forward.

https://www.magyp.gob.ar/conabia/ (form in Spanish)

B) APPROVALS: None. See section C, Innovative biotechnologies, for information on genome edited animals that Argentina has designated as "non-GMO".

C) INNOVATIVE BIOTECHNOLOGIES

Gene edited Cattle: Joint venture between Recombinetics and Kheiron

The American company Recombinetics/Acceligen and the Argentine company Kheiron signed an agreement in June 2019 focused on precision breeding in Argentina, to introduce new commercial traits in cattle derived from elite genetic lines. The intended end goal of this strategic alignment will be commercializing precision-bred animals that generate highly valued germplasm products for the global market with an initial emphasis on adaptability traits for climate change. The use of Recombinetics's genome editing platform, combined with Kheiron's in-vitro embryo production, cloning, and genome editing platform and infrastructure, will allow single generation production of market-ready animals without sacrificing diversity and estimated breeding values for performance. The companies signed an alliance on a series of projects in Argentina that intend to produce multiple animal product lines to solve existing concerns in the cattle industries.

Part of the challenge in using genome editing and cloning methods for genetic improvement is commercial acceptance of innovative breeding. In Argentina, this is made possible, in part, by the GOA's modernized approach to regulation of genome edited animals.

Their first product would be animal breeds with improved heat tolerance and that are hornless. These products have been presented to the Argentine Biosafety Commission CONABIA for their revision in 2019. In their first meeting of May 2020, the Commission recommended that these animals should be considered as "non-GMO."

Genome edited Fish

The U.S. company *AquaBounty* presented a tilapia fish that has been genome edited to increase productivity through faster growth and lower feed requirements. Argentine regulators considered it to be "non-GMO."

D) LABELLING AND TRACEABILITY

The Argentine Rural Society has created a Genealogic Registry for cloned animals to assist owners and prospective owners of cloned animals. However, this is not an official traceability system adopted by the GOA. At present, there is no official traceability system managed by the government.

E) ADDITIONAL REGULATORY REQUIREMENTS

None

F) INTELLECTUAL PROPERTY RIGHTS

The country does not have any specific IPR regulations for animal biotechnology.

G) INTERNATIONAL TREATIES/FORUMS:

None

H)) RELATED ISSUES:

None

PART F. MARKETING

A) PUBLIC/PRIVATE OPINIONS

In general, the development of GE animals has not caused much public comment in Argentina.

However, with the development of new breeding techniques, the Argentine Polo Horse Association has expressed concern about the possible production of GE polo horses.. Of particular concern to the association is that genetic doping, and the misuse of genetic therapies to improve performance, will be the next phase of doping that will face equestrian sports. They requested that an efficient and accurate detection method be developed to deter those who seek to use genetic doping in horses in order to maintain the integrity of the sport.

B) MARKET STUDIES

Post is not aware of any relevant market studies on animal biotechnology in the country.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

A) COMMERCIAL PRODUCTION

To date, Argentina has not yet had any cases of applications for evaluation of any GE microbes for the production of food ingredients.

B) EXPORTS

There are neither official statistics nor estimates on exports of microbial biotechnology products. However, Argentina exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

C) IMPORTS

Argentina imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

D) TRADE BARRIERS

Post is unaware of any significant trade barrier to these kinds of products.

PART H: POLICY

A) REGULATORY FRAMEWORK

Microbial biotechnology is governed by the same legislation as GE plants, animals, and vaccines, and is subject to analysis and approval (see Part A, Regulatory Framework). All activities involving GE organismsused for agro-industrial purposes or in the agricultural context require prior authorization from the Secretariat of Food, Bio economy and Regional Development (Ministry of Agriculture, Livestock and Fisheries), as established in MAGyP Resolution 763/11. Such authorization for the commercialization of GE organisms whether they are plants, animals or microorganisms, is based on three opinions:

1: Evaluation of the risks to agro ecosystems derived from the commercial-scale release of the GE organism under consideration. This assessment is the responsibility of the Coordination of Innovation and Biotechnology and CONABIA, and will be carried out in accordance with the provisions of the regulations in force, depending on whether they are microorganisms, animals or plants: SAYBI Resolutions Nos. 52 and 63 and SABYDR Resolution No. 32/2021, respectively.

2: Evaluation of material for food, human and animal use, which is the responsibility of the National Agrifood Health and Quality Service (SENASA) and the Technical Advisory Committee for the Use of GE organisms (CTAUOGM), in accordance with SENASA Resolution No. 412/02.

http://www.senasa.gob.ar/sites/default/files/normativas/archivos/res_412-2002_english.pdf

3: The economic impacts regarding the commercialization of GE material is in charge of the Under secretariat of Agricultural Markets of the Ministry of Agriculture, Livestock and Fisheries, according to Resolution SAGyP No. 510.

B) APPROVALS

There are no products approved yet. To date, no applications have been received for of microbial biotech-derived organisms for use in food, so there are still no approvals granted for that use.

In the case of enzymes derived from microbial biotech organisms, there is a positive listing in the CAA, Art. 1263, Chapter XVI.

https://www.boletinoficial.gob.ar/detalleAviso/primera/205739/20190417

C) LABELING AND TRACEABLILITY

There are no mandatory labeling regulations for microbial biotech derived in food in Argentina.

D) MONITORING AND TESTING

No sampling or analysis is performed in the case of import/export of processed foods that may contain a microbial biotech derived as an ingredient.

E) ADDITIONAL REGULATORY REQUIREMENTS

N/A

F) INTELLECTUAL PROPERTY RIGHTS (IPR)

GE microorganisms can be patented in Argentina. Wild-type microorganisms cannot be patented, but the methods for their industrial production and agricultural products based on them are patentable.

G) RELATED ISSUES

Nothing to report at the moment.

PART I: MARKETING

A) PUBLIC/PRIVATE OPINIONS:

Post is not aware of any public concern over the use of microbial biotechnology.

B) MARKET ACCEPTANCE/STUDIES:

Post is not aware of any relevant market studies on microbial biotechnology in the country.

Crop	Trait Category	Event	Applicant	Resolution
Soybean	Glyphosate Herbicide Tolerance	40-3-2	Nidera S. A.	<u>SAPyA N°</u> <u>167</u> (25-3-96)
Soybean	Resistance to Glufosinate Ammonium	A2704-12	Bayer S.A.	(2011)
Soybean	Resistance to Glufosinate Ammonium	A5447-127	Bayer S.A.	(2011)
Cotton	Resistance to Lepidoptera	MON 531	Monsanto Argentina S.A.I.C.	<u>SAGPyA</u> <u>N°428</u> (16-7-98).
Cotton	Glypohosate Herbicide Tolerance	MON 1445	Monsanto Argentina S.A.I.C.	<u>SAGPyA</u> <u>N° 32</u> (25-4-01).
Cotton	Resistance to Lepidoptera and Glyphosate Tolerance	MON 1445 x MON 531	Monsanto	(2009
Corn	Resistance to Lepidoptera	176	Ciba-Geigy	<u>SAPyA N°</u> <u>19</u> (16-1-98).
Corn	Glufosinate Ammonium Tolerance	T25	AgrEvo S. A.	<u>SAGPyA</u> <u>N° 372</u> (23-6-98)
Corn	Resistance to Lepidoptera	MON 810	Monsanto Argentina S.A.I.C.	<u>SAGPyA</u> <u>N° 429</u> (16-7-98).
Corn	Resistance to Lepidoptera	Bt 11	Novartis Agrosem S.A.	<u>SAGPyA</u> <u>N° 392</u> (27-7-01).

Annex: GE Crops Approved in Argentina

Corn	Glyphosate Herbicide Tolerance	NK 603	Monsanto Argentina S.A.I.C.	<u>SAGPyA</u> <u>N° 640</u> (13-7-04).
Corn	Resistance to Lepidoptera and Glufosinate Ammonium Tolerance	TC 1507	Dow AgroSciences S.A. and Pioneer Argentina	<u>SAGPyA</u> <u>N° 143</u>
Corn	Glyphosate Herbicide Tolerance	GA 21	Syngenta Seeds S.A.	SAGPyA <u>N° 640</u> (22-08-05)
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera	NK603x MON810	Monsanto	SAGPyA <u>Nº 78</u> (28/08/07)
Corn	Resistance to Lepidoptera and Glufosinate Ammonium and Glyphosate Tolerance	1507 x NK603	Dow AgroSciences S.A. y Pioneer Argentina S.R.L.	SAGPyA <u>N° 434</u> (28/05/08
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera	Bt11 x GA21	Syngenta Seeds S.A.	(2009)
Corn	Resistance to Lepidoptera	MON89034"	Monsanto	(2010)
Corn	Glyphosate Herbicide Tolerance and Resistance to	MON 88017	Monsanto	(2010)

	Lepidoptera			
Corn	Glyphosate Herbicide Tolerance and Resistance to Lepidoptera and Coleoptera	"MON89034x88017"	Syngenta Agro S.A.	(2010)
Corn	Resistance to Lepidoptera	MIR 162	Syngenta Agro S.A.	(2011)
Corn	Resistance to Lepidoptera and Glyphosate and Glufosinate Herbicide Tolerance	Bt11xGA21xMIR162	Syngenta Agro S.A.	(2011)
Corn	Glyphosate Tolerance and herbicides that inhibit ALS	DP-098140-6	Pionneer Arg. S.R.L.	(2011)
Corn	Resistance to Coleoptera	MIR 604	Syngenta Agro S.A.	(2012)
Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Herbicide Tolerance	Bt11xMIR162xMIR604xGA21	Syngenta Agro S.A.	(2012)
Corn	Resistance to Lepidoptera and Coleoptera, and Glyphosate and Glufosinate Herbicide Tolerance	MON 89034 x TC 1507 x NK603	Dow Agro Sciences	(2012)

Corn	Resistance to Lepidoptera and Glyphosate	MON 89034 x NK603	Monsanto	(2012)
Soybean	Resistance to Lepidoptera Glyphosate	MON 87701 x MON 89788	Monsanto	(2012)
Soybean	Resistance to Imidazolinones	CV 127	Basf	(2013)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate Herbicide Tolerance	TC1507xMON810xNK603 y TC1507xMON810	Pioneer Argentina	(2013)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate Herbicide Tolerance	Bt11xMIR162xTC1507xGA21 and all the intermediate stacked	Syngenta Agro S.A.	(2014)
Soybean	Resistance to 2, 4D, Glyphosate and Glufosinate	DAS-44406-6	Dow AgroSciences S.A.	(2015)
Potato	Virus Resistance	SY233	Tecnoplant S.A.	(2015)
Soybean	High oleic content and glyphosate Tolerance	DP-305423 x MON-04032-6	Pioneer Argentina S.R.L.	(2015)
Soybean	Drought Resistance	IND410(Hb4)	INDEAR S.A.	(2015)

Cotton	Resistance to Glyphosate and Ammonium Glufosinate	BCS-GHØØ2-5 x ACS-GHØØ1-3 GHB614xLLCotton25	Bayer S.A.	(2015)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate	TC1507xMON810xMIR162xNK603	Pioneer Argentina S.R.L.	(2016)
Soybean	Resistance to Glyphosate	MON-89788-1	Monsanto Argentina	(2016)
Soybean	Resistance to Lepidoptera	MON-87701-2	Monsanto Argentina	(2016)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate	MON-89034-3 x DAS-01507-1 x MON-00603-6 x SYN-IR162-5	Dow Agro Sciences Argentina	(2016)
Soybean	Resistance to Lepidoptera, Glyphosate and Glufosinate	DAS-81419-2 x DAS-444Ø6-6 and DAS-81419-2	Dow AgroSciences Argentina S.R.L	(2016)
Corn	Resistance to Lepidoptera, Glyphosate and Glufosinate	SYN-BT011-1 x SYN-IR162-4 x MON-89034-3 x MON-00021-9	Syngenta Agrosciences	(2016)
Soybean	Tolerance to glufosinate and enzyme HPPD inhibitors	SYN-000H2-5	Syngenta Agrosciences & Bayer S.A.	2017
Safflower	Expression of bovine pro- quimosin in	IND-10003-4, IND-10015-7, IND- 10003-4 x IND-10015-7	INDEAR	Dec7, 2017

	seeds			
Corn	Tolerance to a herbicides base de 2,4 D and herbicides of the family ariloxifenoxi, ammonium glufosinate and glyphosate. Resistance to Lepidoptera	DAS-40278-9 MON-89034-3 x DAS- 01507-1 x MON-00603-6 x DAS- 40278-9 and all the stacked in between	Dow AgroSciences Argentina S.R.L.	March, 2018
Soybean	Tolerance to herbicides isoxaflutole, glfosate and amonium glufosinato.	MST-FG072-2 y MST-FG072- 2xACS-GM006-4	Bayer S.A.	March, 2018
Corn	Tolerance to glyphosate and to ammonium glufosinate and Resistance to Lepidoptera and Coleoptera	SYN-05307-1 y SYN-BT011-1xSYN- IR162-4xSYN-IR604-5xDAS-01507- 1xSYN-05307-1xMON-00021-9 and all the stacked in between	Syngenta Agro S.A.	March, 2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera y Coleoptera	MON-87427-7, MON-87411-9, MON- 87427-7 × MON-89Ø34-3 × SYN- IR162-4 × MON-87411-9 and all the stacked in between	Monsanto Argentina S.R.L.	May, 2018
Alfalfa	Tolerance to glyphosate and decrease in the content of lignin	MON-ØØ179-5, MON-ØØ1Ø1-8 y MON-ØØ179-5 x MON-ØØ1Ø1-8	INDEAR	July 2018
Soybean	Only for processing (Food, Feed and Processing)	MON-877Ø8-9 x MON-89788-1	MONSANTO	July, 2018

Potato	Resistance to viruses	TIC-AR233-5	Tecnoplant S.A.	August, 2018
Corn	Tolerance to glyphosate and Resistance to Lepidoptera y Coleoptera	MON-87427-7 x MON-89Ø34-3 x MON-88Ø17-3	MONSANTO ARGENTINA S.R.L.	August 2018
Soybean	Tolerance to glyphosate and gluphosinate. Drought Resistance.	IND-ØØ41Ø-5 x MON-Ø4Ø32-6 (OCDE)	INDEAR	October 2018
Cotton	Glyphosate Tolerance and herbicides inhibitors of HPPD	BCS-GH811-4	BASF	February 2019
Soybean	Tolerance to glyphosate and gluphosinate	DBN-Ø9ØØ4-6	INDEAR	February 2019
Corn	Tolerance to herbicides formulated based on products of the family of ariloxifenoxi an 2,4,-D, ammonium gluphosinate and glyphosate, and Resistance to lepidoptera.	MON-89O34x DAS-O1507 x MON - OO603 x SYN-IR162-4 x DAS- 40278-9	DOW Argentina	April 2019
Cotton	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	SYN-IR1Ø2-7 y BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7, the intermediate stacked and the events BCS-GHØØ4-7 y BCS-GHØØ5-8	BASF	June 2019

Corn	Tolerance to glyphosate and gluphosinate. Resistance to lepidoptera	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	MONSANATO + DOW +PIONEER Argentina	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6	MONSANTO ARGENTINA	August 2019
Corn	Tolerance to ammonium gluphosinate, glyphosate and Resistance to lepidoptera	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ603-6	MONSANTO ARGENTINA	September 2019
Cotton	Resistance to insects and lepidoptera	SYN-IR1Ø2-7	Syngenta	October 2019
Wheat	Tolerance to drought and ammonium glufosinate	IND-ØØ412-7	Indear-Bioceres	October 2020
Corn	Resistance to lepidoptera, coleoptera, Tolerance to glyphosate, gluphosinate, and Dicamba	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-87411-9 x MON-87419-8 x MON-ØØ81Ø-6	MONSANTO ARGENTINA	November 2021

Alfalfa	Tolerance to Gliphosate	MON-ØØ163-7	INDEAR	November 2021
Corn	Tolerance to glyphosate, gluphosinate, and Dicamba	MON-87427-7 x MON-87419-8 x MON ØØ6Ø3-6	MONSANTO ARGENTINA	November 2021

Source: <u>https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/ogm-vegetal-eventos-con-autorizacion-comercial</u>

Attachments:

No Attachments